K122966

5. Section 5 - FDA 510(k) Summary

APR 0 8 2013

5.1 General Information

Sponsor:	BTL Industries, Inc. 47 Loring Drive Framingham, MA 01702 Tel: +1-508-309-7948 Fax: +1-508-309-7956
Applicant:	EMERGO Group 816 Congress Avenue Suite 1400 Austin, TX 78701 Tel: +1-512-326-9997 Fax: +1-512-327-9998 project.mamagement@emergogroup.com
Contact Person:	Richard Vincins EMERGO Group, Vice President, QA
Summary Preparation Date:	2 April 2013

5.2 Device Names

Trade/Proprietary Name:	XP200
Primary Classification Name:	Electrosurgical cutting and coagulation device and accessories
Classification Regulation:	878.4400
Product Code:	GEI

5.3 Legally Marketed Predicate Devices

The XP200 system is a state-of-the-art high-frequency energy device with accessories, and is substantially equivalent to the current products that are already cleared for USA distribution under the following 510(k) Premarket Notification numbers:

- EXILIS (K092191)

- Pellevé GlideSafeTM Non-Ablative Wrinkle Treatment System (K102698, K082834)

5.4 Table - Predicate Devices

510(k) number	**Not Assigned**	**K092191 (Attachment 1)**	**K102698 (K082834) (Attachment 3)**
Device name	XP200	EXILIS	Pellevé GlideSafe™ Non-Ablative Wrinkle Treatment System
Company name	BTL Industries, Inc.	BTL Industries, Inc.	Ellman International
Product Code Regulation	General & Plastic Surgery 21 CFR 878.4400 • GEI, Electrosurgical Cutting and Coagulation Device & Accessories.	General & Plastic Surgery 21 CFR 878.4400 • GEI, Electrosurgical Cutting and Coagulation Device & Accessories.	General & Plastic Surgery 21 CFR 878.4400 • GEI, Electrosurgical Cutting and Coagulation Device & Accessories.
Indications for Use	The XP200 device is indicated for the primary treatment of dermatologic procedures for non-invasive treatment of periorbital wrinkles and rhytids.	The EXILIS device is indicated for the primary treatment of dermatologic and general surgical procedures for non-invasive treatment of wrinkles and rhytids. EXILIS is a state-of-the-art device to apply therapy by a non-invasive method of high-frequency field.	Non-ablative treatment of mild to moderate facial wrinkles and rhytides for skin prototypes I-IV.
Device Technologies	Application of heat to the tissue w/ RF energy.	Application of heat to the tissue w/ RF energy.	Application of heat to the tissue w/ RF energy.
Electrical Protection	Class II, BF	Class II, BF	Class I, BF
Unit Construction	Constructed of materials that conform with safety standards and requirements.	Constructed of materials that conform with safety standards and requirements.	Constructed of materials that conform with safety standards and requirements.
Interface	Touch-screen user applied interface to program and set the controls for the patient application; there is a hand-piece utilized to deliver the treatment.	Touch-screen user applied interface to program and set the controls for the patient application; there is a hand-piece utilized to deliver the treatment.	Buttons and knobs on the unit; there is a hand-piece utilized to deliver the treatment.
Color Touch Screen	8.4" (21.5 cm) / 640 × 480 pixels	8.4" (21.5 cm) / 640 × 480 pixels	Not Available
Energy Type	Radiofrequency	Radiofrequency	Radiofrequency
Modes Of Operation	Monopolar	Monopolar	Monopolar mode used for

510(k) number	**Not Assigned**	**K092191 (Attachment 1)**	**K102698 (K082834) (Attachment 3)**
Device name	XP200	EXILIS	Pellevé GlideSafe™ Non-Ablative Wrinkle Treatment System
Company name	BTL Industries, Inc.	BTL Industries, Inc.	Ellman International
			indications for use: (Non-ablative treatment of mild to moderate facial wrinkles and rhytides for skin prototypes I-IV.). Bipolar mode used for other indications for use.
Nominal Operating Power	120 W	170 W	120 W
Operating Temperature	18°C to 30°C	18°C to 30°C	10°C to 40°C
Operating Humidity	60% - 75%	60% - 75%	30% - 75%
Treatment Temperature Range	39°C – 42°C	39°C – 42°C	39°C-42°C
Power Level Adjustable via Applicator	YES	YES	NO
Material of the Generator Case	Aluminum, Plastic, Stainless Steel	Aluminum, Plastic, Stainless Steel	Plastic, Metal
Patch Electrode Contact Quality Monitoring	YES	YES	YES
RF Energy Emission Indicator	YES; Information displayed on the screen of the applicator and on the main screen of the unit.	YES; Information displayed on the screen of the applicator and on the main screen of the unit.	YES
Applicator Dimensions	4.25" × 2.6" × 7" (11 cm × 7 cm × 18 cm)	3.5" × 2.8" × 7.1" (7 cm × 9 cm × 18 cm)	0.8" × 0.8" × 6.3" (2 cm × 2 cm × 16 cm)
Applicator Weight	350 g	500 g (incl. cable)	Less than 100 g
Energy Source	100 – 240 VAC, max 4A, 50 – 60 Hz	100 – 240 VAC, max 5A, 50 – 60 Hz	100 – 240 VAC, max 4A, 50 – 60 Hz
System Dimensions	16" × 10.6" × 11.9" (41 cm × 22 cm × 18 cm)	39" × 24" × 24" (100 cm × 60 cm × 60 cm)	9.5" × 7.1" × 16.5 " (24 cm × 18 cm × 42 cm)
System Weight	16 lb (7.3 kg)	66 lb (30 kg)	26 lb (11.8 kg)

5.5 Product Description

The XP200 device is indicated for the primary treatment of dermatologic procedures for non-invasive treatment of periorbital wrinkles and rhytids. The XP200 system is a state-of-the-art device to apply therapy by a non-invasive method of high-frequency field.

The control unit of the device is fitted with a color touch screen, which significantly facilitates the use of the device. The design of the device enables to see the on-screen information from various positions of the operator. In addition, the brightness of the screen can be set to match the lighting in the room. The on-screen information will guide you through the entire therapy by means of easy setting of parameters using touch-screen buttons and knobs/keys on the device. For easier control, the applicator is equipped with buttons, enabling to operate the device during therapy, and a display, which shows the set and indicated parameters.

Any therapeutic parameter can be set easily by simple use of the touch-screen buttons. During the entire therapy time the device informs you about the therapeutic method, the type of the therapy applied, the set power, and other necessary data.

The XP200 consists of the following main components:

- microprocessor-driven control unit
- high-frequency electromagnetic energy generator
- user interface with 8.4" color touch screen
- applicator with color screen and control buttons

5.6 Indications for Use

The XP200 device is indicated for the primary treatment of dermatologic procedures for non-invasive treatment of periorbital wrinkles and rhytids.

5.7 Non-Clinical Testing

The XP200 has been thoroughly evaluated for electrical, electromagnetic and mechanical safety. Medical device software life cycle processes have been verified and validated as well as output and biocompatibility. The XP200 has been found to conform with applicable medical device safety standards. The system complies with the following standards:

ISO 14971	Medical devices - Application of risk management to medical devices
IEC 62304	Medical Device Software – Software Life Cycle Processes
Medical Electrical Equipment:	
IEC 60601-1	General requirements for safety
IEC 60601-1-2	Collateral Standard: Electromagnetic compatibility – Requirements and Tests
IEC 60601-2-2	Particular requirements for the safety of high frequency surgical equipment
IEC 60601-1-6	General requirements for basic safety and essential performance Collateral standard: Usability

EMC Requirements for Medical Equipment:

IEC 61000-4-2; IEC 61000-4-3; IEC 61000-4-4; IEC 61000-4-5

Biological Evaluation for Medical Devices:

ISO 10993-1; ISO 10993-5; ISO 10993-10

Performance Testing of the BTL Industries XP200:

- Frequency Accuracy and Carrier Wave Form: The testing supports that the RF output frequency of the XPS200 device as compared to the predicate devices are within the accuracy for the product specification. The performance testing demonstrated that the XP200 device delivers the transmit carrier wave in a standard sinusoid form.
- Carrier Wave Nominal Output Power: The measurement of the carrier wave output power produced real-life power output characteristics data that are mutually comparable between the subject device and the predicate devices.
- Power Fluency: The power fluency characteristics between the XP200 device and the predicate devices are equivalent in the linear calculation. The calculation of the difference in power fluency between the XP200 device and the predicate devices are less than 4.8% at 100Ω and less than 8.8% at 150Ω which is within the acceptance criteria for the change value.
- Tissue Heating (Temperature Gradient's Maximum at the Skin Surface): The measurement results demonstrated that the thermal performances of the XP200 device and the predicate devices are nearly identical. Measurements made under

experimental conditions showed that all devices are able to deliver sufficient energy to reach the temperature of 45°C which is in the acceptance criteria.

- Critical thresholds of resistance between two contact areas of a dual dispersive patch electrode when the CQM will shut off the energy delivery reacted at the same level for the XPS200 device and the predicate devices. The value obtained in this test for each device were less than described as a safe level in the Operator's Manual.

5.8 Clinical Testing

A clinical study to evaluate the wrinkle-reducing effects of 3.25-MHz radiofrequency (RF) energy delivered by the XP200 system was completed. There were three (3) sites with three (3) principal investigators that were part of the clinical investigation. The clinical study was completed with the subject going through treatment of four (4) applications at 5-7 day intervals to the human periorbital skin area (eye area) and grading pre- and 90-days post treatment.

There were no adverse events reported with any patient. The XP200 device performed as intended with no reported occurrences with either the patients or the device performance. The XP200 system at 3.25-MHz RF produces consistent, statistically significant reduction in periorbital wrinkles.

5.9 Substantial Equivalence

Based upon the intended use and technical information provided in this pre-market notification, the XP200 and accessories have been shown to be substantially equivalent to currently marketed predicate devices.

5.10 Conclusion

Based on the aforementioned information, the XP200 is safe and effective and substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 8. 2013

BTL Industries, Inc.
% EMERGO Group
Mr. Richard Vincins
611 West 5th Street, Third Floor
Austin, Texas 78701

Re: K122966
Trade/Device Name: XP200
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 21, 2013
Received: March 22, 2013

Dear Mr. Vincins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may therefore; market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 - Indications for Use Statement

510(k) Number (if known): **K122966**

Device Name: **XP200**

Indications for Use: The XP200 device is indicated for the primary treatment of dermatologic procedures for non-invasive treatment of periorbital wrinkles and rhytids.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S For

Division of Surgical Devices
510(k) Number: K122966